

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8592

Bartle, C.J.

January 26, 2011

The Estate of Carole E. Gillen ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have

(continued...)

To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In or around July, 2006, Leesa A. Gillen, the Administrator of the Estate, submitted a supplemental Green Form to the Trust signed by the attesting physician, Robert A. Guyton, M.D. Based on an echocardiogram dated July 12, 2004, Dr. Guyton attested in Part II of the Green Form that Carole E. Gillen ("Ms. Gillen") died as a result of a condition caused by

2. (...continued)
caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d. (1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

valvular heart disease or valvular repair/replacement surgery.⁴

Based on such findings, the Estate would be entitled to

Matrix A-1, Level V benefits⁵ in the amount of \$651,104.⁶

In the report of claimant's March 16, 2002 echocardiogram, the reviewing cardiologist, Winston H. Gandy, Jr., M.D., stated that claimant has "[m]oderate mitral Regurgitation (36% by area trace)." Under the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA").

See id. § I.22.

4. Dr. Guyton also attested that Ms. Gillen suffered from severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, arrhythmias, and a reduced ejection fraction in the range of 50% to 60% and that she had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. Although Dr. Guyton initially indicated that Ms. Gillen suffered from peripheral embolus following surgery, he submitted a "Green Form Part II Question H.2 Clarification" dated May 14, 2007, in which he changed his response to "No." In any event, these conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records[.]" See Settlement Agreement § IV.B.2.c.(5)(c).

6. In 2003, Ms. Gillen received Matrix A-1, Level II benefits in the amount of \$458,369. According to the Trust, if the Estate is entitled to Matrix A-1, Level V benefits, the Estate would be entitled to benefits in the amount of \$1,109,473. The amount at issue, therefore, is the difference between the Level II Matrix Benefits already paid and the amount of Level V Matrix Benefits.

As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.⁷ Specifically, the Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant or representative claimant where the Diet Drug Recipient was diagnosed with mild mitral regurgitation⁸ by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a).

In October, 2007, the Trust forwarded the claim for review to Siu-Sun Yao, M.D., F.A.C.C., one of its auditing cardiologists. As part of his review, Dr. Yao evaluated Ms. Gillen's March 16, 2002 echocardiogram, which formed the basis for Ms. Gillen's original claim for Matrix A-1, Level II benefits. Dr. Yao concluded that the March 16, 2002 echocardiogram revealed only mild mitral regurgitation, stating that:

[Echocardiogram] 3/16/02 - mild [mitral regurgitation]. Gain setting too high. Sonographer overtraced RJA & included trace

7. If the Estate's supplemental claim for Level V benefits is payable only on Matrix B-1, the Estate will not receive any additional payment because the amount the Estate would be entitled to receive for a Matrix B-1, Level V claim is less than the amount received by Ms. Gillen for her Matrix A-1, Level II claim.

8. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

backflow. 2+ mild [mitral regurgitation] in real time.

Based on Dr. Yao's finding of mild mitral regurgitation as to the March 16, 2002 echocardiogram, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁹ In contest, the Estate argued that the claim for Matrix A-1, Level V benefits should be paid because: (1) the Trust concedes that the Estate is entitled to Level V benefits; (2) the Trust previously audited Ms. Gillen's March 16, 2002 echocardiogram and determined that it demonstrated moderate mitral regurgitation; and (3) nothing in the Settlement Agreement permits the Trust to re-review an earlier echocardiogram, which the Trust agreed demonstrated the requisite level of regurgitation in order to reduce a supplemental claim to Matrix B-1.

The Estate also contended that there was a reasonable medical basis for finding that Ms. Gillen's March 16, 2002 echocardiogram revealed moderate mitral regurgitation because three physicians reviewed the echocardiogram and concluded that

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

moderate mitral regurgitation was present. First, the physician who signed Ms. Gillen's original Green Form, Dr. Gandy, and the auditing cardiologist who reviewed Ms. Gillen's original claim, Michael Rihner, M.D., each found that, based on the March 16, 2002 echocardiogram, Ms. Gillen suffered from moderate mitral regurgitation. Second, Ms. Gillen's expert in connection with her original claim, James O. Day, M.D., F.A.C.C., submitted a letter wherein he stated that the March 16, 2002 echocardiogram demonstrated moderate mitral regurgitation of 40%.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On May 6, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7814 (May 6, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on July 29, 2008. Under the Audit Rules it is within the Special Master's

discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for its claim for Matrix A-1, Level V benefits. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of its claim, the Estate reasserts the arguments that it made in contest. In response, the Trust argues that, in the context of a supplemental claim, the Trust properly audited Ms. Gillen's earlier March 16, 2002 echocardiogram because the initial claim for Matrix Benefits was not subject to a complete medical audit. The Trust also maintains that the Estate's supplemental claim is a "wholly separate" claim from the initial claim, which, pursuant to this court's decision in PTO No. 2662 (Nov. 26, 2002), is required to be audited by the Trust. Finally, the Trust asserts that the Estate did not establish a reasonable medical basis for finding that Ms. Gillen's March 16, 2002 echocardiogram demonstrated moderate mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed Ms. Gillen's March 16, 2002 echocardiogram and concluded that there was a reasonable medical basis for finding that it demonstrated moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

There was some degree of mitral regurgitation with a posteriorly directed jet noted in the parasternal long axis view. Visually, mild to moderate mitral regurgitation was noted in the apical four chamber view. I digitized those cardiac cycles in the apical four chamber view in which the mitral regurgitant jet could best be evaluated. I then measured the areas of the RJA and LAA by electronic calipers. The mitral regurgitant jet was noted to be a posterolaterally directed jet within the left atrium. In spite of increased color gain, I was able to planimeter the mitral regurgitant jet area in the mid portion of systole. The largest

representative RJA in the apical four chamber view was 3.5 cm². This determination of the RJA was similar to the RJA measurements of 3.25 cm² and 3.13 cm² by the sonographer on the tape. I measured the LAA in the apical four chamber view. I determined that the LAA was 16.8 cm². Therefore, the largest representative RJA/LAA ratio was 21% qualifying for moderate mitral regurgitation. . . .

* * *

In response to Question 1, there is a reasonable medical basis for the finding that [Ms. Gillen] suffers from moderate mitral regurgitation on the echocardiogram of March 16, 2002. As noted above, although most of the RJA/LAA ratios were less than 16%, the largest representative RJA/LAA ratio was 21%. These measurements were determined with electronic tracing of digitized images.

In response to the Technical Advisor Report, the Estate argues that it established a reasonable medical basis for the representation that Ms. Gillen's March 16, 2002 echocardiogram demonstrated moderate mitral regurgitation. Thus, the Estate contends that it should receive Matrix A-1, Level V benefits.

After reviewing the entire Show Cause Record, we find that the Estate has established a reasonable medical basis for its claim for Matrix A-1, Level V benefits. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-

Certified Cardiologist, supported by medical records[.] " Settlement Agreement § IV.B.2.c.(5)(c). In the present case, the Trust does not contest the Estate's entitlement to Level V Matrix Benefits.

Rather, the Trust asserts that the Estate's Level V claim should be reduced to Matrix B-1. Specifically, the Trust argues that the Estate is entitled only to Matrix B-1 benefits because Ms. Gillen had mild mitral regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a).

Ms. Gillen's original attesting physician, Dr. Gandy, and her expert, Dr. Day, reviewed the March 16, 2002 echocardiogram and found that Ms. Gillen had moderate mitral regurgitation. Dr. Rihner, who audited Ms. Gillen's original Green Form, also determined that she had moderate mitral regurgitation. Although the Trust now challenges these findings, Dr. Vigilante observed that, "[i]n spite of increased color gain, I was able to planimeter the mitral regurgitant jet area in the mid portion of systole." Based on his measurements, Dr. Vigilante concluded that "the largest representative RJA/LAA ratio was 21%." Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34. As previously noted, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement

Agreement § I.22. Under these circumstances, the Estate has met its burden in establishing a reasonable medical basis for the representation that Ms. Gillen's March 16, 2002 echocardiogram demonstrates moderate mitral regurgitation.¹¹

For the foregoing reasons, we conclude that the Estate has met its burden of proving that there is a reasonable medical basis for its claim and is consequently entitled to Matrix A-1, Level V Benefits. Therefore, we will reverse the Trust's denial of the Estate's claim for Matrix Benefits.

11. Accordingly, we need not address the Estate's remaining arguments in support of its claim for Matrix A-1, Level V benefits.